Senate Engrossed House Bill

FILED
MICHELE REAGAN
SECRETARY OF STATE

State of Arizona
House of Representatives
Fifty-second Legislature
Second Regular Session
2016

CHAPTER 293

HOUSE BILL 2310

AN ACT

AMENDING SECTIONS 23-908 AND 32-1963.01, ARIZONA REVISED STATUTES; RELATING TO BIOLOGICAL PRODUCTS.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Section 23-908, Arizona Revised Statutes, is amended to read:

23-908. Injury reports by employer and physician; schedule of fees; violation; classification

A. Every employer that is affected by this chapter, and every physician who attends an injured employee of such employer, shall file with the commission and the employer's insurance carrier from time to time a full and complete report of every known injury to the employee arising out of or in the course of employment and resulting in loss of life or injury. Such a report shall be furnished to the commission and the insurance carrier at times and in the form and detail the commission prescribes, and the report shall make special answers to all questions required by the commission under its rules.

B. The commission shall fix a schedule of fees to be charged by physicians, physical therapists or occupational therapists attending injured employees and, subject to subsection C of this section, for prescription medicines required to treat an injured employee under this chapter. The commission shall annually review the schedule of fees.

C. If a schedule of fees for prescription medicines adopted pursuant to subsection B of this section includes provisions regarding the use of generic equivalent drugs OR INTERCHANGEABLE BIOLOGICAL PRODUCTS, those provisions shall comply with section 32-1963.01, subsections A, B and ~~C~~ D through ~~J~~ L. If the commission considers the adoption of fee schedule provisions that involve specific prices, values or reimbursements for prescription drugs, the commission shall base the adoption on studies or practices that are validated and accepted in the industry, including the applicability of formulas that use average wholesale price, plus a dispensing fee, and that have been made publicly available for at least one hundred eighty days before any hearing conducted by the commission.

D. Notwithstanding section 12-2235, information obtained by any physician or surgeon examining or treating an injured person shall not be considered a privileged communication, if that information is requested by interested parties for a proper understanding of the case and a determination of the rights involved. Hospital records of an employee concerning an industrial claim shall not be considered privileged if requested by an interested party in order to determine the rights involved. Medical information from any source pertaining to conditions unrelated to the pending industrial claim shall remain privileged.

E. When an accident occurs to an employee, the employee shall forthwith report the accident and the injury resulting therefrom to the employer, and any physician employed by the injured employee shall forthwith report the accident and the injury resulting therefrom to the employer, the insurance carrier and the commission.

F. When an accident occurs to an employee, the employer may designate in writing a physician chosen by the employer, who shall be permitted by the employee, or any person in charge of the employee, to make one examination of the injured employee in order to ascertain the character and extent of the injury occasioned by the accident. The physician so chosen shall forthwith report to the employer, the insurance carrier and the commission the character and extent of the injury as ~~ascertained by him~~ THE PHYSICIAN ASCERTAINS. If the accident is not reported by the employee or ~~his~~ THE EMPLOYEE'S physician forthwith, as required, or if the injured employee or those in charge of ~~him~~ THE EMPLOYEE refuse to permit the employer's physician to make the examination, and the injured employee is a party to the refusal, no compensation shall be paid for the injury claimed to have resulted from the accident. The commission may relieve the injured person or ~~his~~ THAT PERSON'S dependents from the loss or forfeiture of compensation if it believes after investigation that the circumstances attending the failure on the part of the employee or ~~his~~ physician to report the accident and injury are such as to have excused them.

G. Within ten days after receiving notice of an accident, the employer shall inform the insurance carrier and the commission on such forms and in such manner as may be prescribed by the commission.

H. Immediately on notice to the employer of an accident resulting in an injury to an employee, the employer shall provide the employee with the name and address of the employer's insurance carrier, the policy number and the expiration date.

I. Any person failing or refusing to comply with this section is guilty of a petty offense.

Sec. 2. Section 32-1963.01, Arizona Revised Statutes, is amended to read:

32-1963.01. Substitution for prescription drugs or biological products; requirements; label; definitions

A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection ~~D~~ E of this section, a pharmacist may fill the prescription with a generic equivalent drug.

B. A PHARMACIST MAY SUBSTITUTE A BIOLOGICAL PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT ONLY IF ALL OF THE FOLLOWING CONDITIONS ARE MET:

1. THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS DETERMINED THE SUBSTITUTED PRODUCT TO BE AN INTERCHANGEABLE BIOLOGICAL PRODUCT.

2. THE PRESCRIBING PHYSICIAN DOES NOT DESIGNATE IN WRITING OR ELECTRONICALLY THAT SUBSTITUTION IS PROHIBITED IN A MANNER PURSUANT TO SUBSECTION E OF THIS SECTION.

3. THE PHARMACY INFORMS THE PATIENT OR PERSON PRESENTING THE PRESCRIPTION OF THE SUBSTITUTION PURSUANT TO SUBSECTION C OF THIS SECTION.

4. WITHIN FIVE BUSINESS DAYS AFTER DISPENSING A BIOLOGICAL PRODUCT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE MAKES AN ENTRY OF THE

SPECIFIC PRODUCT PROVIDED TO THE PATIENT, INCLUDING THE NAME OF THE PRODUCT AND THE MANUFACTURER. THE COMMUNICATION SHALL BE CONVEYED BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, AN ELECTRONIC PRESCRIBING TECHNOLOGY, A PHARMACY BENEFIT MANAGEMENT SYSTEM, OR A PHARMACY RECORD. ENTRY INTO AN ELECTRONIC RECORDS SYSTEM AS DESCRIBED IN THIS PARAGRAPH IS PRESUMED TO PROVIDE NOTICE TO THE PRESCRIBER. OTHERWISE, THE PHARMACIST SHALL COMMUNICATE THE BIOLOGICAL PRODUCT DISPENSED TO THE PRESCRIBER USING FAX, TELEPHONE, ELECTRONIC TRANSMISSION OR OTHER PREVAILING MEANS, EXCEPT THAT COMMUNICATION IS NOT REQUIRED IF ONE OF THE FOLLOWING APPLIES:

(a) THERE IS NO INTERCHANGEABLE BIOLOGICAL PRODUCT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR THE PRODUCT PRESCRIBED.

(b) A REFILL PRESCRIPTION IS NOT CHANGED FROM THE PRODUCT DISPENSED ON THE PRIOR FILLING OF THE PRESCRIPTION.

5. THE PHARMACY RETAINS A RECORD OF THE BIOLOGICAL PRODUCT DISPENSED PURSUANT TO SECTION 32-1964, SUBSECTION A.

~~B.~~ C. Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug OR BIOLOGICAL PRODUCT prescribed and the generic equivalent drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT, if both of the following apply:

1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

2. The transaction is not subject to third-party reimbursement.

~~C.~~ D. The pharmacist shall place on the container the name of the drug OR BIOLOGICAL PRODUCT dispensed followed by the words "generic equivalent for" OR "INTERCHANGEABLE BIOLOGICAL PRODUCT FOR" followed by the brand or trade name of the product that is being replaced by the generic equivalent DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter.

~~D.~~ E. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute",~~"~~ OR "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.

~~E.~~ F. This section applies to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments.

~~F.~~ G. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic equivalent drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT or TO substitute any specific generic equivalent drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT for a brand name drug OR BIOLOGICAL PRODUCT against the professional judgment of the pharmacist or the order of the prescriber.

~~G.~~ H. The liability of a pharmacist in substituting according to this section ~~shall be~~ IS no greater than that ~~which is~~ incurred in the filling of a generically written prescription. This subsection does not limit or diminish the responsibility for the strength, purity or quality of drugs provided in section 32-1963. The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

~~H.~~ I. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic EQUIVALENT drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT has shown that:

1. All products dispensed have an expiration date on the original package.

2. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective drugs OR BIOLOGICAL PRODUCTS.

J. THE BOARD SHALL MAINTAIN ON ITS PUBLIC WEBSITE A LINK TO THE CURRENT LIST OF EACH BIOLOGICAL PRODUCT DETERMINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE AN INTERCHANGEABLE BIOLOGICAL PRODUCT.

~~I.~~ K. The labeling and oral notification requirements of this section do not apply to pharmacies serving patients in a health care institution as defined in section 36-401. However, in order for this exemption to apply to hospitals, the hospital must have a formulary to which all medical practitioners of that hospital have agreed and that is available for inspection by the board.

~~J.~~ L. For the purposes of this section:

1. "BIOLOGICAL PRODUCT" HAS THE SAME MEANING PRESCRIBED IN 42 UNITED STATES CODE SECTION 262.

~~1.~~ 2. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.

~~2.~~ 3. "Formulary" means a list of medicinal drugs.

~~3.~~ 4. "Generic equivalent" or "generically equivalent" means a drug that has an identical amount of the same active chemical ingredients in the same dosage form, that meets applicable standards of strength, quality and purity according to the United States pharmacopeia or other nationally recognized compendium and that, if administered in the same amounts, will provide comparable therapeutic effects. Generic equivalent or generically equivalent does not include a drug that is listed by the ~~federal~~ UNITED STATES food and drug administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

5. "INTERCHANGEABLE BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT THAT EITHER:

(a) THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS LICENSED AND DETERMINED MEETS THE SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY PURSUANT TO 42 UNITED STATES CODE SECTION 262(k)(4).

(b) IS DETERMINED TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN THE LATEST EDITION OF THE SUPPLEMENT TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS.

Sec. 3. Effective date

This act is effective from and after December 31, 2016.

APPROVED BY THE GOVERNOR MAY 17, 2016.

FILED IN THE OFFICE OF THE SECRETARY OF STATE MAY 17, 2016.

Passed the House February 4, 2016

by the following vote: 56 Ayes,

1 Nays, 3 Not Voting

Speaker of the House

Pro Tempore

Chief Clerk of the House

Passed the Senate March 24, 2016

by the following vote: 29 Ayes,

0 Nays, 1 Not Voting

President of the Senate

Secretary of the Senate

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF GOVERNOR

This Bill received by the Governor this

_____ day of _____, 20_____

at _____ o'clock _____M.

_____
Secretary to the Governor

Approved this _____day of

_____

at _____o'clock _____M.

_____
Governor of Arizona

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF SECRETARY OF STATE

This Bill received by the Secretary of State

this _____ day of _____, 20_____

at _____ o'clock _____M.

_____
Secretary of State

H.B. 2310

HOUSE CONCURS IN SENATE
AMENDMENTS AND FINAL PASSAGE

May 6, 2016,

by the following vote: 56 Ayes,

1 Nays, 4 Not Voting

Speaker of the House

Jim Drache
Chief Clerk of the House

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF GOVERNOR

This Bill was received by the Governor this

7 day of May, 2016

at 1:18 o'clock A. M.

Valerie Harnna
Secretary to the Governor

Approved this 17th day of

May, 2016,

at 1:09 o'clock P. M.

Doug A. Ducey
Governor of Arizona

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF SECRETARY OF STATE

This Bill was received by the Secretary of State

this 17th day of May, 2016

at 4:35 o'clock P M.

Michele Reagan
Secretary of State

H.B. 2310